

Editorial

Concept of Materiovigilance in Unani Medicine

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These days, it is obligatory by all medicine regulatory bodies to enforce strategies to improve and protect the health and safety of patients, therefore, concepts like Pharmacovigilance, Cosmetovigilance, Herbovigilance, Haemvigilance and Materiovigilance are being taken up and incorporated as National Health Program in most of the countries.

Materiovigilance is a science to follow any incidents that might result from using medical devices. Medical device as defined by WHO¹ means any instrument, apparatus, implement, machine, appliance, implant, reagent for *in-vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) like diagnostic, prevention, control, treating or diminishing an illness, compensating an injury, handicap, or for modifying physiological process.

In India, medical devices are notified as Drugs under Drugs & Cosmetics Act 1940. Section 3 (b) (iv) defines, Medical Devices as “Devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals”.² GMP Requirements are specified under Schedule M III. Rule 109-A defines Labeling of Medical Devices, while Rule 125-A is to maintain standards for medical devices. At present, provisions related to import, manufacture, distribution and sale of medical devices are covered under the Drugs and Cosmetics Act 1940 and the Drugs and Cosmetics Rules 1945.²

The Poly Implant Prothèse breast implant affair and controversies surrounding metal-on-metal hips have focused the attention of the public and clinicians on medical device regulation and the safety of implants.³ Likewise, after several horrific cases of malfunctioning medical devices in India, such as babies being burnt to death due to short circuits in

incubators or hip implants causing blood poisonings, etc., the Ministry of Health and Family Welfare, Govt. of India, has approved a commencement of “Materiovigilance Programme of India (MvPI)” vide approval dated 10th February 2015 in an effort to ensure safety of medical devices.⁴ It has been launched by Drug Controller General of India (DCGI) on 6th July 2015 at Indian Pharmacopoeia Commission (IPC), Ghaziabad. IPC is National Coordination Centre for MvPI⁵. Sree Chitra Tirunal Institute of Medical Sciences and Technology (SCTIMST), Thiruvananthapuram, is assigned to function as National Collaborating Centre for MvPI, while Technical Support is provided by National Health System Resource Centre (NHSRC) for MvPI. Under the MvPI, all health stake holders are supposed to report any dysfunction or any change of the characteristics and or performance of a device, any inadequacy in the labeling or instructions, which might lead to risk, death or serious relapse in the state of health of a patients, a user or a third party. Any technical or medical reasons related to the characteristics or performance of a device can also be reported.

In Unani Medicine⁶, it is very common to prepare different medicines in different metallic utensils. These utensils need frequent polishing and die-casting to avoid direct contact with metal and eventually metal poisoning. The metallic “Magical Bowls” are often used for drug administration to enhance drug efficacy. Similarly, it is very critical to make compounded powder (*Safoof*) of medicinal products as fine as possible. Safoof, defined as solid material in a finely divided state, is useful in making many medicines such as *Majun*, *Khamira*, *Jawarish*, *Sharbat*, *Hab*, etc. The equipment used to make medicinal powder are *Kharal* (Mortar and Pestle), *Hawan Dasta* (Hand-grinder) and *Sil Batta* (Grindstone). The mortar and pestle are of different

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types such as stone, quartz, wood, iron, brass, steel and porcelain. Stones are either of hard or soft in nature e.g. *Sang Simaq* (Simaq Stone), *Sang Khara* (Granite Stone), *Sang Siyah* (Black Stone), *Sang Marmar* (Marble Stone) and *Sang Yashab* (Jasper Stone). If a mortar and pestle of soft stone is used for grinding hard stone-based medicines (*Hajariyat*) and jewel-based medicines (*Jawaharat*), then chances of contamination with fine pieces of soft stones are more and consequently increase the weight of powder. For example if the original weight of medicine was 25 gram, then its grinding by using soft stone mortar would increase the powder to 26 gm. This means that extra weight of soft stone is added with medicine. This extra ingredient may be harmful and may lead to toxicity and mortality.

It is thus advised in Unani pharmacy (*Saidla*) that while making powder of hard medicine, grind it by

using hard stone mortar and pestle, similarly, soft medicines be grinded and powdered by using soft black and marble stones.⁷ Similarly Jaques, et. al. in 1946 reported silica, which is a major constituent of sand and quartz, accelerates blood coagulation by adsorption and partial denaturation of a specific plasma protein, the Hageman factor.⁸ This classical instruction enabled Unani physicians to eliminate or change the chosen mortar and pestle, with an intention of constantly improving the quality of medical devices and providing patients and users with increased safety. In this way we can say that the modern concept of monitoring and safety of medical devices which is known materiovigilance was quite documented in Unani System of medicine.

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